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EXAMINER	
SISSON, BRADLEY L	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 03/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/070,297	TOCQUE ET AL.	
	Examiner	Art Unit	
	Bradley L. Sisson	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-43* is/are pending in the application.

4a) Of the above claim(s) *43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

2. This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

3. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 27-33, drawn to a process or *in vitro* detection of the presence of a pathological condition in a subject; claim 34, drawn to a nucleic acid-based method of *in vitro* detection of blood cells characteristic of a pathological condition; claims 35-39, drawn to a process for preparing a nucleic acid library; claims 40-41 drawn to a library and claim 42, drawn to a kit comprising said library.

Group II, claim(s) 43, drawn to a protein-based *in vitro* method of detecting a disease in a subject.

4. The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The inventions of Group I has as a special technical feature a library of nucleic acids. In contrast, the invention of Group II does not require such a special technical feature and therefore. Lacks unity of invention with the inventions of Group I.

5. During a telephone conversation with Richard Armstrong, Reg. No. 54,590, on 04 February 2004 a provisional election was made without traverse to prosecute the invention of Group I, claims 27-42. Affirmation of this election must be made by applicant in replying to this Office action.

6. Claim 43 has been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

8. The specification is objected to as documents have been improperly incorporated by reference. It is noted with particularity that the instant disclosure makes reference to various foreign patent document, both published and unpublished, as well as non-patent publications which are in turn being relied upon for disclosing how he claimed invention is to be made and used. In support fo this position, attention is directed to page 17, lines 15-17; page 18, lines 17-24; page 19, lines 17-19; page 20, lines 11-14; and page 28, lines 12-14. A review of the disclosure fails to locate where any of these cited documents has been incorporated by reference. As set forth in *Advanced Display Systems Inc. v. Kent State University* (Fed. Cir. 2000) 54 USPQ2d at 1679:

> Incorporation by reference provides a method for integrating material from various documents into a host document--a patent or printed publication in an anticipation determination--by citing such material in a manner that makes it clear that the material is effectively part of the host document as if it were explicitly contained therein. *See General Elec. Co. v. Brenner*, 407 F.2d 1258, 1261-62, 159 USQP 335, 337 (D.C. Cir. 1968); *In re Lund*, 376 F.2d 982, 989, 153 USPQ 625, 631 (CCPA 1967). **To incorporate material by reference, the host document must identify with detailed particularity what specific material it incorporates and clearly indicate where that material is found in the various documents.** *See In re Seversky*, 474 F.2d 671, 674, 177 USPQ 144, 146 (CCPA 1973) (providing that incorporation by reference requires a statement "clearly identifying the subject matter which is incorporated and where it is to be found"); *In re Saunders*, 444 F.2d 599, 602-02, 170 USPQ 213, 216-17 (CPA 1971) (reasoning that a rejection or anticipation is appropriate only if one reference "expressly incorporates a particular part" of another reference); *National Latex Prods. Co. v. Sun Rubber Co.*, 274 F.2d 224, 230, 123 USPQ 279, 283 (6th Cir. 1959) (requiring a specific reference to material in an earlier application in order to have that material considered a

part of a later application); *cf. Lund*, 376 F.2d at 989, 13 USPQ at 631 (holding that **a one sentence reference to an abandoned application is not sufficient to incorporate from the abandoned application into a new application**). (Emphasis added.)

9. While the specification has been found to identify various documents, the specification does not teach that these or any other document identified in the specification has been properly incorporated by reference. Accordingly, the documents cited and seemingly relied upon by applicant have not been considered either as prior art or as satisfying the enablement, written description, or best mode requirements of 35 USC 112, first paragraph.

Claim Objections

10. A series of singular dependent claims is permissible in which a dependent claim refers to a preceding claim which, in turn, refers to another preceding claim.

11. A claim, which depends from a dependent claim, should not be separated by any claim, which does not also depend from said dependent claim. In the present case, claim 42, which depends from independent claim 27, is separated from claim 27 by independent claims 34, 35, and 40. It should be kept in mind that a dependent claim may refer to any preceding independent claim. In general, applicant's sequence will not be changed. See MPEP § 608.01(n).

12. Claim 37 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. As presently worded, the method of claim 35, the claim from which claim 37 depends, requires one to recover hybrids from the hybridization reaction mixture.

It stands to reason that if there exists but hybridized and non-hybridized portions, and when one of said portions is removed, then second (unhybridized) portion is also effectively removed or recovered. Given such, claim 37 does not further limit claim 35 from which it depends.

13. Alternatively, claim 37 could be considered to broaden claim 35 in that it suggests that the characteristic nucleic acid preparation is derived from recovered unhybridized nucleic acids (both reference and non-reference). In contrast, claim 35 sates that the hybridized nucleic acids are to be considered characteristic of a pathological condition.

Claim Rejections - 35 USC § 112

14. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

15. Claims 27-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Attention is directed to the decision of *Vas-Cath Inc. v. Mahurkar* 19 USPQ2d 1111 (CAFC, 1991):

> This court in *Wilder* (and the CCPA before it) clearly recognized, and we hereby reaffirm, that 35 USC 112, first paragraph, requires a "written description of the invention" which is separate and distinct from the enablement requirement. The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the "applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the "written description" inquiry, *whatever is now claimed*.

16. For convenience, claims 27, 34, 35, and 40, the only independent claims, are reproduced below.

27. A process for the detection *in vitro* of the presence of a pathological condition in a subject, comprising (i) providing a sample of blood cells from the subject, wherein said blood cells comprise lymphocytes, macrophages, monocytes or dendritic cells, (ii) preparing nucleic acids from the sample and (iii) hybridizing all or part of the nucleic acids so prepared with at least one nucleic acid library in order to obtain a hybridization profile, the nucleic acid library comprising a plurality of nucleic acid clones specific for splicing forms of genes, the splicing forms being characteristic of blood cells in said pathological condition, the hybridization profile indicating the presence of blood cells in the sample characteristic of the pathological condition, thereby detecting the presence of said pathological condition in said subject.

34. A process of detection *in vitro* of blood cells characteristic of the presence of a pathological condition, comprising (i) providing a sample of blood cells from the subject, wherein said blood cells comprise lymphocytes, macrophages, monocytes or dendritic cells, (ii) preparing nucleic acids from the sample and (iii) hybridizing all or part of the nucleic acids so prepared with at least one nucleic acid library in order to obtain a hybridization profile, the nucleic acid library comprising a plurality of nucleic acid clones specific for splicing forms of genes, the splicing forms being characteristic of blood cells in said pathological condition, the hybridization profile indicating the presence of blood cells in the sample characteristic of the pathological condition.

35. A process of preparation of a nucleic acid library characteristic of a pathological condition, wherein said process comprises (i) obtaining a first nucleic acid preparation from blood cells isolated from an organism presenting a pathology, said blood cells comprising lymphocytes, macrophages, monocytes or dendritic cells, (ii) obtaining a reference nucleic acid preparation from blood cells isolated from an organism not presenting said pathology, (iii) hybridizing said first preparation and said reference preparation and (iv) recovering, from the hybrids formed in (iii), nucleic acids characteristic of blood cells from the organism in a pathological condition.

40. A library of nucleic acid clones, wherein said library comprises nucleic acid clones specific for genes whose level of expression or splicing is modified in a blood cell from an organism in a pathological situation.

17. As see above in claims 27 and 34, one is to use a "at least one nucleic acid library" that comprises "a plurality of nucleic acid clones specific for splicing forms of genes." In accordance with claim 35, one is to utilize "a reference nucleic acid preparation from blood cells isolated from an organism not presenting said pathology," and in claim 40, it is seen that applicant is claiming outright a "library of nucleic acid clones [that] comprises nucleic acid clones specific for genes whose level of expression or splicing is modified in a blood cell from an organism in a pathological situation."

18. For purposes of examination, the term "organism" has been interpreted as encompassing any and all life forms, and that the "pathological condition" encompasses any and all forms of pathology where the expression level of said genes can be directly or indirectly related to the pathological condition(s).

19. In accordance with claim 41, the "cancer" or "neurodegenerative disease" is considered to encompass any and all forms of "cancer" and "neurodegenerative diseases," in any life form that is capable of exhibiting any "cancer" or "neurodegenerative disease."

20. In accordance with claim 42, the "organism" is considered to encompass any life form that has any blood cell, regardless of whether the organism uses iron, copper or some other system for oxygen transport.

21. A review of the disclosure fails to find where any library of a "plurality of clones of nucleic acid clones specific for splicing forms of genes" has been adequately described, regardless of the source organism. While page 20 of the specification asserts that nucleic acid banks can comprise 10 to 50,000 clones, the specification does not provide an adequate written description of any of these clones. It appears that applicant is replying upon obviousness to

satisfy the written description requirement of 35 USC 112, first paragraph. It would appear that applicant is attempting to satisfy the written description requirement of 35 USC 112, first paragraph, through obviousness. Obviousness, however, cannot be relied upon for satisfaction of the written description requirement. In support of this position, attention is directed to the decision in *University of California v. Eli Lilly and Co.* (Fed. Cir. 1997) 43 USPQ2d at 1405, citing *Lockwood v. American Airlines Inc.* (Fed. Cir. 1997) 41 USPQ2d at 1966:

> Recently, we held that a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement of that invention.

22. While applicant has attempted to define the nucleic acids in terms of their being "splicing forms of genes" such functional language does not adequately describe just what each of the specific nucleic acid molecules is. Attention is directed to the decision in *University of Rochester v. G.D. Searle & Co., et al.* (Fed. Cir. February 13, 2004):

> The "written description" requirement serves a teaching function, as a "quid pro quo" in which the public is given "meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time." Enzo, 323 F.3d at 970.
>
> ***
>
> While it is true that this court and its predecessor have repeatedly held that claimed subject matter "need not be described in haec verba" in the specification to satisfy the written description requirement, e.g., In re Smith, 481 F.2d 910, 914 (CCPA 1973), it is also true that the requirement must still be met in some way so as to "describe the claimed invention so that one skilled in the art can recognize what is claimed." Enzo, 323 F.3d at 968. We have further explained that:
>
> > [T]he appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement. . . . A description of an anti-inflammatory steroid, i.e., a steroid (a generic structural term) described even in terms of its function of lessening inflammation of tissues fails to distinguish any steroid from others having the same activity or function. A description of what a material does, rather than of what it is, usually does not suffice. [Regents of the Univ. of Cal. v.] Eli Lilly [& Co., Inc.], 119 F.3d [1559,] 1568 [(Fed. Cir. 1997) ("Lilly")] . . . . The disclosure must allow one skilled in the art to

> visualize or recognize the identity of the subject matter purportedly described. Id.
>
> ***
>
> We of course do not mean to suggest that the written description requirement can be satisfied only by providing a description of an actual reduction to practice. Constructive reduction to practice is an established method of disclosure, but the application must nonetheless "describe the claimed subject matter in terms that establish that [the applicant] was in possession of the . . . claimed invention, including all of the elements and limitations." Hyatt v. Boone, 146 F.3d 1348, 1353 (Fed. Cir. 1998). But see Enzo, 323 F.3d at 969 ("Application of the written description requirement, however, is not subsumed by the 'possession' inquiry. A showing of 'possession' is ancillary to the statutory mandate that '[t]he specification shall contain a written description of the invention,' and that requirement is not met if, despite a showing of possession, the specification does not adequately describe the invention."). The specification must teach the invention by describing it.

Attention is also directed to the decision of *Fiers v. Sugano* 25 USPQ2d 1604-5 (CAFC, January 1993) wherein is stated:

> We also reject *Fiers* argument that the existence of a workable method for preparing a DNA establishes conception of that material. Our statement in *Amgen* that conception may occur, *inter alia*, when one is able to define a chemical by its method of preparation requires that the DNA be claimed by its method of preparation. We recognize that, in addition to being claimable by structure or physical properties, a chemical material can be claimed by means of a process. A product-by-process claim normally is an after-the-fact definition, used after one has obtained a material by a particular process. Before reduction to practice, conception only of a process for making a substance, without a conception of a structural or equivalent definition of that substance, can at most constitute conception of the substance claimed as a process. Conception of a substance claimed *per se* without reference to a process requires conception of its structure, name, formula, or definitive chemical or physical properties. . .
> * * * *
> The difficulty that would arise if we were to hold that a conception occurs when one has only an idea of a compound, defining it by its hoped-for function, is that would-be inventors would file patent applications before they had made their inventions and before they could describe them. That is not consistent with the statute or the policy behind the statute, which is to promote disclosure of inventions.

Attention is also directed to the decision of *University of California v. Eli Lilly and Co.* (CA FC, July 1997) 43 USPQ2d 1398 wherein is stated:

> In claims involving chemical materials, generic formulas usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate written description of the claimed genus. In claims to genetic material, however, a generic statement such as "vertebrate insulin cDNA" or "mammalian cDNA," without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is See Fiers, 984 F.2d at 1169-71, 25 USPQ2d at 1605-06 (discussing Amgen). It is only a definition of a useful result rather than a definition of what it achieves as a result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. *See In re Wilder*, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.
>
> Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA. See Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606.

23. In the present case applicant is claiming both methods that require the use of nucleic acid libraries (claims 27-34) as well as the nucleic acid libraries outright (claims 40-42), each of which libraries can comprise an infinite number of "nucleic acids specific for splicing forms of genes" (page 20, line 6, of the disclosure indicates that they can each comprise 50,000 clones), and that these clones can be derived from any and all life forms, or "organisms." The specification has not been found to provide an adequate written description of any clone, much less a library comprised of tens of thousands (or more) of said clones. Without said libraries, one is not able to practice the claimed methods of detection. Indeed, without an adequate written

description of the libraries, the libraries *per se*, and kits that comprise same (claim 42) are not adequately supported by the disclosure. Aside from not providing an adequate written description of the claimed libraries of nucleic acid clones, the specification does not reasonably suggest that applicant was in possession of the claimed invention at the time of filing.

24. Claims 35-39, as noted above, are drawn to a method whereby "a nucleic acid library characteristic of a pathological condition" is prepared. As noted above, the "pathological condition" has been interpreted as encompassing any pathological condition in any animal that has any form of "blood," which encompasses worms, fishes, amphibians, reptiles, mammals, etc. Said "pathological condition" is not required or limited to that which is known and/or even associated with any one or more genes in any respect. In particular, the "pathological condition" may well be that of a localized infection, yet the nucleic acid clones produced in accordance with the recited method steps is derived from blood cells of an organism. Similarly, the nucleic acid isolated for the "reference" as well as the nucleic acid isolated from the "organism" presenting pathology are both taken from blood cells. The specification does not provide an adequate written description of how nucleic acid from blood cells is indicative of pathological conditions that arise out of a localized infection or a somatic mutation elsewhere (e.g., basal cell carcinoma). Further, the specification dos not provide an adequate written description as to how normal/control/reference nucleic acid that hybridizes to complementary sequences from the "organism presenting a pathology" are to in fact be "characteristic of a pathological condition" when by definition they are the equivalent of the reference nucleic acid of an organism not presenting the pathology (claim 36).

25. As presented above, the "pathological condition" need not be known, or even indirectly associated with genes of the organism. The specification does not provide an adequate written description of how one is to determine if an organism is manifesting a previously unknown pathological condition, or is to be considered eligible for being a source of "reference nucleic acid preparation," when one does not know how to recognize the pathological condition which in fact is being demonstrated.

26. In accordance with claims 35-39, the organism presenting the pathological condition and the organism not presenting the pathological condition need not be related to one another; e.g., a human with bone cancer could be the organism with the pathological condition while an earthworm could well satisfy as a source for reference nucleic acid preparation. The specification has not provided an adequate written description as to how such evolutionary diverse organisms, including those for which it would be impossible for them to demonstrate the pathological condition, are to be selected and utilized as a source for reference nucleic acids.

27. Claim 38 requires one to recover "nucleic acid clones specific for splicing forms of genes." The method clearly encompasses known and unknown genes. The specification does not provide an adequate written description of all splicing forms of genes, or how they are to be isolated and bound to a solid support over that of other nucleic aid hybrids, which in accordance with claim 35 are also characteristic of the pathological condition.

28. For the above reasons, and in the absence of convincing evidence to the contrary, claims 27-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

29. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

30. Claims 35-39 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: that which will result in a generic "nucleic acid library characteristic of a pathological condition."

31. In accordance with claim 35 one is to prepare "a nucleic acid library characteristic of a pathological condition." Said pathological condition has been interpreted as being virtually any pathological condition, known and unknown, both related and unrelated to the organism's genetic makeup. Claim 35 culminates not in the aforementioned generic nucleic acid library but rather in one that that is now limited to being "characteristic of blood cells from the organism in a pathological condition." Applicant is urged to amend the claims such that the intended product of the method and the resultant product are one and the same.

Double Patenting

32. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

33. Claims 35-39 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 and 14 of U.S. Patent No. 6,251,590 B1 (Schweighoffer et al.). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims result in the production of nucleic acid preparation characteristic of pathological condition.

34. Claims 27-35 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,372,432 B1 (Tocque et al.). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims result in the detection of a pathological condition.

Conclusion

35. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

36. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

37. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
03 March 2004